

Services to make and publish rules and regulations necessary to the efficient administration of the functions that are assigned to the Secretary under the Act.

(4) Section 1871 of the Act authorizes the Secretary to prescribe regulations as may be necessary to carry out the administration of the Medicare program under title XVIII.

(b) *Scope.* This subpart sets forth—

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs; and

(3) The terms of the agreement with CMS and the basis for and the effect of de-certification.

(4) The requirements for an OPO to be re-certified.

§ 486.302 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a recipient, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended recipient.

Agreement cycle refers to the time period of at least 4 years when an agreement is in effect between CMS and an OPO.

Certification means a CMS determination that an OPO meets the requirements for certification at § 486.303.

Death record review means an assessment of the medical chart of a deceased patient to evaluate potential for organ donation.

Decertification means a CMS determination that an OPO no longer meets the requirements for certification at § 486.303.

Designated requestor or effective requestor is an individual (generally employed by a hospital), who is trained to handle or participate in the donation consent process. The designated requestor may request consent for dona-

tion from the family of a potential donor or from the individual(s) responsible for making the donation decision in circumstances permitted under State law, provide information about donation to the family or decision-maker(s), or provide support to or collaborate with the OPO in the donation consent process.

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation.

Donor after cardiac death (DCD) means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death may be termed a non-heartbeating or asystolic donor.

Donor document is any documented indication of an individual's choice in regard to donation that meets the requirements of the governing state law.

Eligible death for organ donation means the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

- (1) Active infections (specific diagnoses).
 - (i) Bacterial:
 - (A) Tuberculosis.
 - (B) Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis.
 - (ii) Viral:

(A) HIV infection by serologic or molecular detection.

(B) Rabies.

(C) Reactive Hepatitis B Surface Antigen.

(D) Retroviral infections including HTLV I/II.

(E) Viral Encephalitis or Meningitis.

(F) Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia.

(G) Acute Epstein Barr Virus (mononucleosis).

(H) West Nile Virus infection.

(I) Severe acute respiratory syndrome (SARS).

(iii) Fungal:

(A) Active infection with *Cryptococcus*, *Aspergillus*, *Histoplasma*, *Coccidioides*.

(B) Active candidemia or invasive yeast infection.

(iv) Parasites: active infection with *Trypanosoma cruzi* (Chagas'), *Leishmania*, *Strongyloides*, or *Malaria* (*Plasmodium* sp.).

(v) Prion: Creutzfeldt-Jacob Disease.

(2) General:

(i) Aplastic Anemia.

(ii) Agranulocytosis.

(iii) Extreme Immaturity (<500 grams or gestational age of <32 weeks).

(iv) Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease.

(v) Previous malignant neoplasms with current evident metastatic disease.

(vi) A history of melanoma.

(vii) Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma.

(viii) Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation.

(ix) Active Fungal, Parasitic, viral, or Bacterial Meningitis or encephalitis.

(3) The number of eligible deaths is the denominator for the donation rate outcome performance measure as described at § 486.318(a)(1).

Eligible donor means any donor that meets the eligible death criteria. The

number of eligible donors is the numerator of the donation rate outcome performance measure.

Entire metropolitan statistical area means a metropolitan statistical area (MSA), a consolidated metropolitan statistical area (CMSA), or a primary metropolitan statistical area (PMSA) listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census. CMS does not recognize a CMSA as a metropolitan area for the purposes of establishing a geographical area for an OPO.

Expected donation rate means the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas. This rate is adjusted for the following hospital characteristics: Level I or Level II trauma center, Metropolitan Statistical Area size, MS Case Mix Index, total bed size, number of intensive care unit (ICU) beds, primary service, presence of a neurosurgery unit, and hospital control/ownership.

Observed donation rate is the number of donors meeting the eligibility criteria per 100 deaths.

Open area means an OPO service area for which CMS has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

Organ procurement organization (OPO) means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs.

Re-certification cycle means the 4-year cycle during which an OPO is certified.

Standard criteria donor (SCD) means a donor that meets the eligibility criteria for an eligible donor and does not meet the criteria to be a donor after cardiac death or expanded criteria donor.

Transplant hospital means a hospital that provides organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or

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more types of organ transplant centers operating within the same transplant hospital.

Urgent need occurs when an OPO's noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.

REQUIREMENTS FOR CERTIFICATION AND DESIGNATION

§ 486.303 Requirements for certification.

In order to be certified as a qualified organ procurement organization, an organ procurement organization must:

(a) Have received a grant under 42 U.S.C. 273(a) or have been certified or re-certified by the Secretary within the previous 4 years as being a qualified OPO.

(b) Be a non-profit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986.

(c) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals.

(d) Have an agreement with CMS, as the Secretary's designated representative, to be reimbursed under title XVIII for the procurement of kidneys.

(e) Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.

(f) Have procedures to obtain payment for non-renal organs provided to transplant centers.

(g) Agree to enter into an agreement with any hospital or critical access hospital in the OPO's service area, including a transplant hospital that requests an agreement.

(h) Meet the conditions for coverage for organ procurement organizations, which include both outcome and process performance measures.

(i) Meet the provisions of titles XI, XVIII, and XIX of the Act, section 371(b) of the Public Health Services Act, and any other applicable Federal regulations.

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§ 486.304 Requirements for designation.

(a) Designation is a condition for payment. Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made to an OPO by a hospital only if the OPO has been designated by CMS as an OPO.

(b) An OPO must be certified as a qualified OPO by CMS under 42 U.S.C. 273(b) and § 486.303 to be eligible for designation.

(c) An OPO must enter into an agreement with CMS in order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid.

§ 486.306 OPO service area size designation and documentation requirements.

(a) *General documentation requirement.* An OPO must make available to CMS documentation verifying that the OPO meets the requirements of paragraphs (b) through (d) of this section at the time of application and throughout the period of its designation.

(b) *Service area designation.* The defined service area either includes an entire metropolitan statistical area or a New England county metropolitan statistical area as specified by the Director of the Office of Management and Budget or does not include any part of such an area.

(c) *Service area location and characteristics.* An OPO must define and document a proposed service area's location through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area.

(3) The number and the names of all hospitals and critical access hospitals in the service area that have both a ventilator and an operating room.

§ 486.308 Designation of one OPO for each service area.

(a) CMS designates only one OPO per service area. A service area is open for competition when the OPO for the